510(k) Summary

OCT 1 6 2008

Date: 8-11-2008

1. Company making the submission

	Submitter
Name	Kyungwon Medical Co.,Ltd
Address	Suite 601 World Meridian Venture Center, 60-24 Gasan-Dong, Geumcheon-Gu, Seoul, Korea 153-801
Phone	+82-2-2113-8693~8
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Contact	Shim, JaeBum Ph.D. Technical Director
Website	http://www.kyungwonmedical.co.kr

2. Device:
   Trade Name: PolyBone® Granule & Block
   Common Name: Bone Void Filler
   Classification Name: Resorbable Calcium Salt Bone Void Filler

3. Predicate Device: Kasios TCP, Vitoss Scaffold.

4. Description:

   PolyBone® Granule & Block is a synthetic resorbable calcium phosphate bone void filler consisted of 99.99% beta-tricalcium phosphate, and 0.01% polyphosphate. It is an osteoconductive material which provides a porous scaffold upon which bone formation can occur. The multidirectional interconnected porosity ranges from 75~85% with a 200~500 μm pore size.

   Mechanism of PolyBone® Granule & Block's bone regeneration works by bone cells resorbing polyphosphate, which is a bone regenerating palpation material. Indication for use of PolyBone® Granule & Block is a filler of bone void regions.

   The device is available in a variety of shape and sizes.

5. Indication for use:
PolyBone® Granule & Block is indicated only for filling bone voids or defects that are not intrinsic to the stability of the bony structure. PolyBone® Granule & Block is to be gently packed into bony voids or gaps of the skeletal system (such as extremities, spine and the pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. PolyBone® Granule & Block is a bone graft substitute that resorbs and is replaced with bone during the healing process.

6. Review:
PolyBone® Granule & Block has the similar technological characteristics to the predicate device; components, indication for use, chemical and performance properties.

Components Similarities
All devices are packed with a container

Indication for Use Similarities
All devices have the same indication for use

Chemical Similarities
All devices are made up from β-Tricalcium phosphate family

Performance Properties Similarities
All devices are for filling bone voids or defects that are not intrinsic to the stability of the bony structure.

Biocompatibility
The biocompatibility of PolyBone® Granule & Block has been performed by ISO10993-1:2003; cytotoxicity, sensitization, irritation, intracutaneous reactivity, systemic toxicity, subchronic toxicity, genotoxicity and implantation. The testing results show PolyBone® Granule & Block to be biologically safe.

7. Conclusion
Based on the information provided in this premarket notification Kyungwon Medical Co.,Ltd. Concludes that PolyBone® Granule & Block is safe and effective and substantially equivalent to predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2008

Kyungwon Medical Co., Limited
% Kodent, Inc.
Jung Bae Bang
US Agent
13340 East Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K082338
Trade/Device Name: PolyBone® Granule & Block
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: August 11, 2008
Received: August 15, 2008

Dear Jung Bae Bang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known) K082338

Device Name: PolyBone® Granule & Block

Indications for Use:

PolyBone® Granule & Block is indicated for filling bone voids or defects that are not intrinsic to the stability of the bony structure. PolyBone® Granule & Block is to be packed into bony voids or gaps of the skeletal system (such as extremities, spine and the pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. PolyBone® Granule & Block is a bone graft substitute that resorbs and it replaced with bone during the healing process.

Prescription Use_____X_____ AND/OR Over-The-Counter Use_____
(21CRF 801 Subpart D) (21CRF 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082338